IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

ROBLYN MILLER and JOHN MILLER, Plaintiffs, v. AMERICAN MEDICAL SYSTEMS, INC., Defendant.	)	CIVIL ACTION FILE NO. _____

ORIGINAL COMPLAINT

Come now Roblyn Miller and John Miller as Plaintiffs herein and hereby file this Complaint, showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiffs are citizens of Cobb County, Georgia.

2. Defendant American Medical Systems, Inc. ("AMS") is a Delaware corporation with its corporate headquarters in Minnesota. All acts and omissions of AMS as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. AMS does not have a registered agent in Georgia, but may be served through its officer Anthony

P. Bihl, III at American Medical Systems, Inc., 10700 Bren Road West, Minnetonka, MN 55343.

3. Plaintiffs are seeking damages in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

4. Defendant is subject to *in personam* jurisdiction in the U.S. District Court for the Northern District of Georgia because it placed a defective product in the stream of commerce and that product caused personal injuries to Roblyn Miller at her residence in the State of Georgia.

FACTUAL ALLEGATIONS

5. Defendant designs, manufactures, markets, packages, labels and sells medical devices, including a medical device known as the MiniArc™ (hereinafter "Product"), a medical device implanted to treat certain women like Plaintiff for stress urinary incontinence.

6. Plaintiff was implanted with a Product designed, manufactured, marketed, packaged, labeled, sold, and placed in the stream of commerce by Defendant. Due to defective design, defective manufacturing, defective marketing, and negligence by Defendant, the Product has caused Plaintiff severe and permanent bodily injuries and significant mental and physical pain and suffering, and economic losses, including infections, inflammation,

vaginal discharge, dyspareunia (painful sexual intercourse), and continued incontinence.

7. The Product and the surgical mesh used to manufacture the Product have numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to:

a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.

b. The mesh material harbors infections that adversely affect human tissues and patient health.

c. The Product and the mesh migrate from the location of their implantation, adversely affecting tissues and patient health.

d. The mesh material abrades tissues adversely affecting patient health.

e. The Product and the mesh regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.

f. Due to their various defects, the Product and the mesh regularly cause significant injury to patients such that the Product must be removed, resulting in additional surgery.

g. The Product and the mesh become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to organs and tissues, adversely affecting patient health.

h. The Product is defective in shape, composition, weight, physical, chemical and mechanical properties and is inappropriately engineered for use in the female pelvis.

8. Because of its numerous defects, the Product creates an unreasonable risk of injury and other adverse health consequences for patients, including, but not necessarily limited to, vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscess.

9. Prior to the time that the Product was implanted into Plaintiff, Defendant was aware of numerous defects in the Product and the mesh, including, but not limited to, the defects and unreasonable risks identified above. Despite being aware of the numerous defects and unreasonable risks in its product, Defendant manufactured, marketed, and distributed the

Product with the intent that it would be implanted in patients. Defendant was aware that implanting the Product in patients was likely to cause injury and harm to the patients into whom the Product was implanted. Alternatively, Defendant failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Product into patients.

10. Defendant made public statements in the form of written product descriptions, product labels, promotional materials and other materials that asserted that implanting the Product in patients was safe and would not cause harm to patients. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Product and that the Product would be implanted in patients. When Defendant made these statements, Defendant knew that the statements were inaccurate. Alternatively, when Defendant made these statements Defendant should have known the statements were inaccurate.

11. Representatives of Defendant also made statements to numerous individuals, including medical professionals, that implanting the Product in patients was safe and would not cause harm to patients. When Defendant's

representatives made these statements, Defendant knew that the statements were inaccurate. Alternatively, when Defendant's representatives made these statements, Defendant should have known the statements were inaccurate.

12. Defendant knowingly and deliberately made material misrepresentations to the federal Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the Product.

13. Before Plaintiff suffered the injuries complained of herein, Defendant was on notice of numerous bodily injuries caused by the Product, and based thereon, Defendant knew or should have known that the Product caused an unreasonably high rate of vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscess in women implanted with the Product.

14. Even though Defendant has known or should have known that the Product created a foreseeable, unreasonable risk of harm to those women into whom it was implanted, Defendant continued to market the Product in the United States. Defendant has sold thousands of Product in the United States alone.

15. Defendant has never provided adequate warning or information of the risks that the Product causes an unreasonably high rate of vaginal erosion,

infection, extrusion, perforation, chronic pain and/or abscess to physicians who implanted the Product, or to women implanted with the device.

COUNT I - STRICT LIABILITY - DEFECTIVE MANUFACTURE

16. One or more of the defects in the Product is the result of improper or incorrect manufacturing processes that result in the Product as manufactured deviating from its intended design. The defects caused by manufacturing defect rendered the Product unreasonably dangerous to consumers and to Plaintiff. The defects in the Product implanted in Plaintiff existed from its manufacture; therefore the defects were present when it left the possession and control of Defendant. As a direct and proximate result of the defective manufacture of the Product, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT II - STRICT LIABILITY - DEFECTIVE DESIGN

17. The Product is unreasonably dangerous and dangerously defective as designed because as designed it has numerous defects that adversely affect patient health. The defects in the Product existed from its inception, therefore the defects were present when it left the possession and control of Defendant. The foreseeable risks of harm posed by the design of the Product could have been reduced and/or avoided by the adoption of a

reasonable alternative design by Defendant, and the failure of Defendant to adopt a safer alternative design rendered the Product unreasonably unsafe. As a direct and proximate result of the defective design of the Product, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT III - STRICT LIABILITY – MARKETING DEFECT

18. The Product was defective by reason of failure of Defendant to provide adequate warnings or instructions.

19. Defendant failed to provide such warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Product or to those women who had been implanted with the Product, concerning the following risks, of which Defendant had actual or constructive knowledge at the time the Product left Defendant's control:

a. the high failure rate of the product;

b. the high rate of infections and abscesses caused by the product;

c. the high rate of vaginal erosions and extrusions caused by the product;

d. the high rate of chronic pain caused by the product

e. the necessity to remove the Product from the patient's body in the event of product failure, infections, abscesses, erosion, or extrusion.

20. After receiving notice of numerous bodily injuries resulting from the Product, Defendant failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Product or those women who had been implanted with the Product that the product was causing an unreasonably high rate of infections, abscesses, erosions and/or extrusions. Furthermore, Defendant failed to provide post-marketing or post-sale warnings or instructions concerning the necessity to remove the Product from the patient's body in the event of product failure, infections, abscesses, erosion, or extrusion.

21. As a direct and proximate result of the inadequate warnings and instructions by Defendant, both at the time of marketing and after the sale of the Product, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT IV – NEGLIGENCE

22. Defendant failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the Product and Defendant negligently failed to provide adequate warnings and instructions to Plaintiff or to her physician regarding the Product.

23. As a direct and proximate result of the negligence of Defendant, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT V – BREACH OF WARRANTY

24. The Product implanted in Plaintiff failed to function as intended and as represented by Defendant because it did not relieve the symptoms or otherwise alleviate the medical problems that it was intended to cure. Instead, the Product caused Plaintiff to suffer infection or inflammation, tissue abrasion, and other severe adverse health consequences. Accordingly, the Product was not fit for the ordinary purpose for which such goods are used and failed to conform to the affirmations or representations of Defendant. Furthermore, Defendant knew that the Product was to be used for the particular purpose for which it was used on Plaintiff and knew that the expertise of Defendant was relied upon to furnish suitable goods.

Because the Product failed to conform to representations and was not suitable for the purpose for which it was used, Defendant has breached express warranties, the implied warranty of merchantability, and the warranty of fitness for a particular purpose. As a result of Defendant's breach of warranty, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT VI – LOSS OF CONSORTIUM

25. Plaintiffs hereby incorporate and reaver all of the allegations contained in the foregoing paragraphs of this Complaint in their entirety as if fully rewritten herein.

26. Plaintiff John Miller is the spouse of Plaintiff Roblyn Miller, and as a direct and proximate result of Defendant's conduct as described in this Complaint, Plaintiff John Miller has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

27. As a direct and proximate result of Defendant's conduct as described in this Complaint, Plaintiff John Miller suffered and in the future will suffer the loss of his wife's affection, companionship, services, society and other damages.

28. As a direct and proximate result of Defendant's conduct as described in this Complaint, Plaintiff is entitled to and hereby seeks all such compensatory damages, punitive damages, attorney fees, reimbursement for all past, present and future health and medical care costs related to the Product, and any and all other damages allowed by law, in an amount to be determined at trial.

PUNITIVE DAMAGES

29. At the time Defendant designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Product and failed to adequately warn Plaintiff of the dangerous and defective nature of the Product and thereby caused Plaintiff's injuries, Defendant knew, or in the exercise of the appropriate degree of care should have known, that its conduct created a high degree of probability of injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiff, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

WHEREFORE, Plaintiffs demand trial by jury, judgment against Defendant for compensatory and punitive damages as well as costs, attorney

fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFFS DEMAND A TRIAL BY JURY.

Date: March 21, 2012

Respectfully submitted,

/s/ Mark R. Mueller
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Font Certification

Pursuant to Local Rule 7.1 D, I hereby certify that the foregoing document was prepared using Times New Roman 14 point type as provided in Local Rule 5.1B.

/s/ Mark R. Mueller
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